



Together, we can save a life

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December 6, 2002

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Marlene H. Dortch
Office of the Secretary
Federal Communications Commission
445 12th Street, SW.
Room TW-A325
Washington, DC 20544

FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF THE SECRETARY

RE: Proposed Rules: *Rules and Regulations Implementing the Telephone Consumer Protection Act (TCPA) of 1991* [CC Docket No. 02-278, CC Docket No. 92-90, FCC 02-250; 67 FR 62667, October 8, 2002]

Dear Secretary Dortch:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comment on the Federal Communication Commission's (FCC) proposal: *Rules and Regulations Implementing the Telephone Consumer Protection Act (TCPA) of 1991* (proposal or proposed TCPA rule).

The Red Cross is an independent, non-profit organization dedicated to saving lives, easing suffering and restoring hope at home and around the world. One division of Red Cross, Biomedical Services, supplies approximately half of the nation's blood for transfusion needs, through its 36 Blood Services regions. Our primary focus is providing high quality blood and blood components, including human plasma derivatives, to patients who need them. The Red Cross is also a large supplier of human allograft tissue including heart valves, skin, bone and associated connective tissues. Additionally, we are engaged in research and other efforts to support collection and processing of such human-derived donations as umbilical cord blood and bone marrow for use in treatment of malignancies and other serious diseases.

The FCC Proposal

As part of the effort to provide blood and tissue for medical treatment, the Red Cross routinely contacts persons who have been donors in the past as well as potential new donors to request that they volunteer to give one of the most important gifts of themselves that they have. The elements of the FCC proposal that may impact the American Red Cross Biomedical Services include suggestions that the FCC:

“refine... existing rules on the use of autodialers, prerecorded messages, and unsolicited facsimile advertisements...and... reconsider the option of establishing a national do-not-call list...” [62668 - Synopsis of NPRM]

Although the FCC is seeking information on a number of topics, this letter emphasizes responding to the requests for comments on:

1. *“...practices used to market goods and services over the telephone and facsimile machine...[and requests comments on]...those entities not covered by the FTC’s proposed national do-not-call data base...”* [62668 – Synopsis of NPRM]
2. *“...what, if any legitimate business or commercial speech interest is promoted by these calls.”* [62669 – TCPA Rules – Company-Specific Do-Not-Call Lists] and
3. *“...calls made jointly by nonprofit and for-profit organizations and whether they should be exempt from the restrictions on telephone solicitations and prerecorded messages.”* [62673 – Tax Exempt Nonprofit Organizations]

Red Cross Response

In response to the request for comments noted above:

1. Communications to request donations of human blood, tissues and related biologic materials are **not** performed in order *“to market goods and services over the telephone....”* Red Cross engages in computer assisted telephone scheduling of active blood donors, and makes telephone requests for participation by new donors. In addition as a non-profit, the Red Cross is not subject to the Federal Trade Commission (FTC) rulemaking, and we’ve requested clarification that the non-profit exclusion will be extended to for-profit telemarketing firms contacting blood donors on our behalf. For the reasons described in this letter and in the attached letters to the FTC, the Red Cross urges the FCC to avoid attempting to fill this perceived gap.
2. We cannot think of a more *“legitimate business or commercial speech interest”* than reaching out to the potential donor population to ask them to give this life-saving gift. Moreover, our records indicate that telephone contact with donors is the single most effective approach to a successful blood collection drive. “I received a call asking me to donate” is the number one reason people tell us they donated.
3. Given the uncertainty in projecting when or where additional blood shortages may occur, reliance on for-profit telemarketing services is crucial to our ability to maintain an adequate blood supply. In these situations, the for-profit partner is not marketing any goods or services of its own, and the final rule should clearly distinguish this relationship from true joint sales-solicitation calls.

Below we describe why we strongly urge the FCC to clarify that it will not subject telephone solicitations for blood or tissue donations to a final rule.

The Blood Supply

Voluntarily donated units of whole blood are separated into specific components such as red blood cells and platelets which are distributed to thousands of hospitals and other health care providers in the United States. Each donation is used to treat up to three people including patients who suffer from a range of serious conditions such as cancer, trauma, surgery, and sickle cell anemia. Plasma from blood donations is made into derivatives as Intravenous Immune Globulin, Factor VIII, and Albumin which are used to treat hemophilia patients, patients with a range of serious debilitating immune deficiencies and patients with other serious conditions such as burns and major injury. It is not an exaggeration to say that blood donations help save the lives of tens of thousands of patients each year.

The blood supply is tenuous, at best. Currently, Red Cross inventories are at a one to two day supply of the most needed blood types. Periodic shortages occur throughout the year, resulting in urgent appeals to blood donors and, occasionally, delays of elective surgery. The projections are for continued increasing demand for blood as the population ages, and a worsening shortfall in collections.

The adequacy and maintenance of the blood supply has been the subject of intense scrutiny within the highest levels of the Federal Government. For example, the September 5, 2002 meeting of the Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability was dedicated to the availability and monitoring of the blood supply.¹ Members of the blood banking community provided their latest data and suggestions for supporting blood availability. The Committee was made aware, once again, of the uncertainties of the blood supply and the critical need for sufficient numbers of volunteer donors.

The Committee's resolutions, which were forwarded directly to the Secretary of HHS, included recommendations that:

- HHS promote increased public awareness of the ongoing need for blood donation,
- fund research on education and other approaches to encouraging donation, and
- support efforts to monitor the blood supply.

¹ The full transcript of the September 5, 2002 meeting may be viewed at:
<http://www.hhs.gov/bloodsafety/transcripts/20020905.html>.

We urge the FCC to consider the impact of their proposals. The FCC may inadvertently *restrict* the ability to solicit blood donations at the same time that another part of the Federal Government, HHS, is *encouraging* blood donation -- two diametrically opposed policies.

Red Cross' Active Donor Solicitation and Do Not Call Practices

The Red Cross maintains a computerized list of blood donors for use in our regional blood centers throughout the nation. This nationwide data base was developed using industry standards for such factors as safeguarding confidentiality and validation techniques. Once a donor is identified, their name, phone number and other relevant information are placed on the donor data base. We routinely generate lists of donors from the data base to help us decide which to contact. For example, we may use the data base to identify and solicit donors with a certain blood type to meet a special patient need.

Any blood donor, at any time, and for any reason, may ask to be excluded from receiving calls. The Red Cross will honor that donor's request by suppressing that donor's name from future recruitment lists. Evidence that the Red Cross is actively maintaining a comprehensive program is demonstrated by the over 90,000 blood donors on our list who have requested us to limit or restrict calling to their households.

Under our internal do-not-call process, donors have the option of limiting both the number and frequency of telephone contacts. For example, a donor may indicate that they are only to be contacted by the sponsor of their local blood drive. They may **tell** us to call them only during the day at their work telephone number or to contact them solely through the mail. **A** donor may specify that they only be called when their particular blood type is in short supply or they may tell us not to call them without specifying any reason at all.

The Red Cross process is far superior to a national or state do-not-call list in that it allows the over 30 different do-not-call or call-limiting options to people who want to continue to be blood donors without being subjected to over recruitment. **A** national or state run do-not-call list offers donors only one option -- to be removed from the list and never be contacted for a blood donation again **regardless of any blood shortages or immediate blood needs**. In almost all cases, our donors tell us that they prefer to be offered options that meet their privacy needs while supporting the needs of hospital patients.

A requirement to monitor and track a nation-wide or state-wide do-not-call list directly duplicates our existing system. Moreover, it fails to provide the customization and meet the standards that our blood donors have come to expect from our donor recruitment operations.

FTC Proposals

In the attached public comment letters on similar proposals by the Federal Trade Commission (FTC), we provide additional explanations of the use of blood donations.² The letters also describe the shortages we continuously face and the potential ramifications for blood donation solicitation if telemarketing and/or do-not-call regulations are established. Specific points include:

- It is far more cost-effective to use telecommunications technologies to reach out to potential blood donors than to conduct individual solicitations.
- The entire health care industry is attempting to meet the needs of an increasingly aging population with tighter budgets and lower insurance reimbursement levels than ever. The additional effort to verify records of a do-not-call registry will add an extremely severe cost burden for many health care providers and their patients.
- There are already a number of Food and Drug Administration regulations regarding donor recruitment as well as advertising and promotional labeling of the blood products. These regulations help avert many of the abuses that led to proposals for the do-not-call registry and help define appropriate donor recruitment practices.

Conclusion

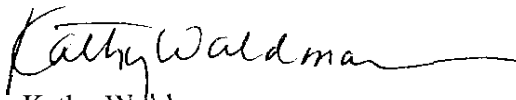
The Red Cross requests that the FCC recognize the critical need for human blood, tissue and related biologic materials as part of the health care system, and ensure its regulatory requirements do not impede efforts to contact donors.

Recommendation #1	The Red Cross urges FCC to clarify that restrictions on telephone solicitations or technologies will not pertain to recruitment of donors of <u>human</u> blood, tissue and related biologic materials.
Recommendation #2	The Red Cross urges clarification that solicitations for donations of human blood, tissue or related biologic materials, including those by for-profit vendors on the behalf of non-profit organizations, will be exempt from any do-not-call list requirements.

² The Red Cross requests inclusion of our letters to the FTC with the rulemaking record for the FCC proposal.

On behalf of the American Red Cross, thank you for the opportunity to comment on the proposed rule. We hope these comments are constructive as you consider further rulemaking. If you have any questions, please contact one of us, or Bill Finlayson, Director of Telemarketing, Donor Strategy, at (360) 891-3121

Sincerely,



Kathy Waldman
Vice President
Regulatory Compliance and
Quality Systems



Radha Muthiah
Vice President
Donor Strategy
Biomedical Services

Attachments



Together, we can save a life

June 28, 2002

Office of the Secretary
Room 159
FTC File No. R411001
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

**RE: Telemarketing Rulemaking--User Fee Comment. FTC File No. R411001
(67 FR 37362; May 29, 2002)**

Dear Secretary Klark:

The American Red Cross Biomedical Services (Red Cross) appreciates this opportunity to provide public comment on the Federal Trade Commission's (FTC) proposed rule, *Telemarketing Sales User Fees*.

Description of the Red Cross and Our Request

The American Red Cross is an independent, non-profit organization dedicated to saving lives, easing suffering and restoring hope at home and around the world. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. Our primary focus is providing high quality blood and blood products to the patients who need them, but the Red Cross is also a large supplier of human allograft tissue including heart valves, skin, bone and associated connective tissues. Additionally, we are engaged in research and other efforts to support donation and processing of such human derived products as umbilical cord blood and bone marrow for use in treatment of malignancies and other serious diseases.

In our letter to the FTC on April 9, 2002 providing public comments on the related rule titled: *Proposed Rulemaking to Amend the Federal Trade Commission's Telemarketing Sales Rule* (TSR) Red Cross noted that, as a non-profit organization, it was our understanding that we would not have to access the proposed national "do-not-call" registry when solicitations for blood donations or charitable contributions were made by Red Cross employees. (See attached letter) Furthermore, it was our understanding that proposed changes to the TSR resulting from language contained in the USA PATRIOT Act (section 1011(b)(3)) would not apply to the Red Cross when blood donations and charitable contributions were being solicited by Red Cross employees. In our comments of April 9, 2002, we requested clarification on these two points. We further

requested an exemption from the proposed changes to the TSR (67 FR 4491, Jan. 30, 2002) for calls made by for-profit telemarketing firms on behalf of the Red Cross when soliciting blood donations.

As stated earlier and in the information provided below, there is an urgent need to ensure there are no impediments to making contact with blood donors. We wish to take this opportunity to reaffirm our request for clarification that for-profit vendors calling on behalf of the Red Cross for blood donations would not need to access a national "do-not-call" registry and are consequently not subject to the "user fee" proposal. Similarly, we request clarification that the exemption from the "do-not-call" registry would apply to solicitations by For-profit vendors for donations of human tissue.'

Blood Donation and Usage

Our blood donors' voluntary gifts make it possible for the Red Cross to collect, process and distribute nearly half the nation's blood supply, over 6 million units of whole blood, each year. Blood collection for transfusion is conducted throughout the nation by 36 regional Red Cross blood centers, utilizing several hundred registered auxiliary collection sites, and daily mobile collection sites throughout local communities.

Units of whole blood are processed into specific components such as red blood cells, platelets, and other products that are distributed to thousands of hospitals and other health care providers in the United States. These products are used to treat patients who suffer from a range of serious conditions such as cancer, trauma, surgery, and sickle cell anemia.

Approximately 1,000,000 liters of plasma recovered from Red Cross volunteer blood donors are annually processed or fractionated into plasma derivatives. These plasma derivatives, including Factor VIII, immune globulin intravenous, and albumin, are distributed under the American Red Cross label to hospitals, hemophilia treatment centers, and other providers.

Factor VIII is a vital infusible drug for hemophilia patients administered for prevention and control of bleeding. Immune globulins offer critical therapy to patients with a range of serious debilitating immune deficiencies such as primary immunodeficiency disease, B-cell chronic lymphocytic leukemia, and idiopathic thrombocytopenic purpura. Dosing of these products can occur up to three times per week. The indications for the infusion of albumin include hypovolemia (with or without shock), hypoalbuminemia due to a wide variety of conditions such as malnutrition, burns, major injury, cirrhosis with ascites, nephrosis, and thyrotoxicosis.

Once the serious, and frequently life-threatening, nature of the health issues faced by the patients who use these products is understood, the need for maintaining an adequate supply of blood can

¹ The Red Cross also concurs with the statement made in the Comments of the Direct Marketing Association, Inc. and the U.S. Chamber of Commerce filed on April 15, 2002 which states: "the Commission should apply only the disclosure provisions of the TSR to charities that employ for-profit firms soliciting contributions for charitable purposes"

be appreciated. We hope this information will support our view of the urgent need to ensure there are no impediments to making contact with our donors, including contact by third parties, to support providing these products to the patients who need them.

Blood Shortages and Donor Recruitment

Blood donors are solicited through a variety of methods. Approximately 70% volunteer to donate by way of a blood mobile or a blood drive at another location, such as a workplace site. Approximately 30% of our donors are identified directly through telemarketing techniques.

Characteristically, the supply of blood is tenuous. While the Red Cross was able to maintain close to a 10-day supply for a number of months after the outpouring of generous gifts following the September 11th tragedy, as of this writing, our national blood inventory is nearing seriously low levels. Many Regions are reporting a day's supply or less of O negative blood and A negative and B negative blood at 1.8 and 1.5 days respectively. Our Rh negative inventories are at 50% of ideal levels. This trend is likely to follow a typical seasonal pattern of shortages keenly felt during the summer months, when many donors elect to spend time on vacations or are otherwise unavailable to donate.

The blood shortage has reached such critical levels that this week, the Red Cross and several other organizations, including the American Association of Blood Banks, America's Blood Centers, the American Public Health Association and the American Hospital Association have issued a joint appeal for blood donations. (See attached News Release)

In addition to the immediate shortages, the Red Cross and other blood collection establishments are facing more fundamental changes in the nature of the available donor population. These changes will continue to contribute to the difficulty of donor recruitment over the longer term. Among them are new restrictions on acceptable donors due to the need to avoid those with the potential exposure to newly identified transmissible diseases. Corporate downsizings have limited the number of people available for worksite blood drives, and restrictions on remaining employee time may also reduce the total donor pool.

All this occurs at a time when the demand for blood is projected to increase with the aging of the population and advances in medical technologies. These advances will improve the public's health, but present a challenge to blood organizations whose services help make the improvements possible.

The Red Cross is examining new, innovative, and cost-effective means of recruiting blood donors. New techniques for using electronic and other alternative media to recruit donors, as well as cold calling potential blood donors and increasing outsourcing to third parties are all under consideration.

It is far more cost-effective to hire a third party for a short-term blood donor recruitment program or to help alleviate seasonal shortages than to hire and maintain a full time staff of donor recruiters year-round. Such trained third party professionals offer expertise and operational

efficiencies that cannot be rapidly duplicated by Red Cross to respond to the volatile demand for blood. The Red Cross's greatest concern is that this rule would severely constrain our ability to outsource blood donor recruitment.

In addition to the urgent need to grant maximum flexibility to use third party telemarketing firms to help maintain an adequate blood supply, the Red Cross urges FTC to consider the following points in support of our request:

- The Food and Drug Administration (FDA) has already established a significant number of regulatory requirements designed, in part, to protect blood donors and consumers from the practices leading to the Telemarketing rulemaking. The donor must give of their time to come to an FDA registered donation center. Further, the Red Cross does not engage in any donation pressure techniques. Such tactics are highly discouraged to avoid inclusion of unsuitable blood donors. Rather, donors must meet numerous FDA defined criteria designed to identify their suitability as a blood donor, as well as pass a mini-health exam. Any financial involvement is severely constrained by FDA's regulations for labeling the blood as "volunteer" versus "paid" which has the effect of banning any donor "incentive" that is readily convertible to cash.
- Many forms of blood donation recruitment communications are also subject to FDA regulations governing advertising and promotional materials, one of the purposes of which is to help limit the abuses the FTC rules were intended to control.
- The requirement to obtain and "scrub" names based on the "do-not-call" registry will be prohibitively expensive for non-profit blood centers. On an ongoing basis, we will need to cross compare our continuously changing blood donor lists to the continuously changing "do-not-call" registry to ensure that our third party telemarketers avoid contacting anyone on the registry. Even if we overcame the financial limitations, the delays in contacting these donors while the lists are being continuously reconciled may result in further reducing the very fragile supply levels just at the time when blood donor telemarketing services are most needed to alleviate a shortage.
- The Red Cross and other blood collection centers follow very stringent donor confidentiality practices, including the standards set by the American Association of Blood Banks (AABB),⁴ the blood banking community's professional association. Depending on the information needed to perform the "scrubbing," we may not be able to carry out this function without risking a violation of these confidentiality practices.

² See 21 C.F.R. § 606.121(c) and FDA's *Compliance Policy Guidance for FDA Staff and Industry on Blood Donor Classification Statement, Paid or Volunteer Donor* (67 FR 35121; May 17, 2002).

³ See 21 C.F.R. §§ 201, 202, 606.120, and 606.122, as well as Sections 201, 502(a) and 502(f) of the Food Drug and Cosmetic Act.

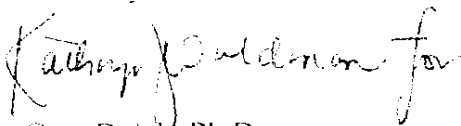
⁴ See AABB standard 5.3.1 - *Care of donors, private and confidential donor qualification process*; 6.22.2 - *Confidentiality of donor and patient records*; and Hpc 9.3 - *Computer systems; provisions to maintain appropriate levels of confidentiality and privacy*.

- Blood donors may be forced *to* choose between placing themselves on the nationwide "do-not-call" registry and inclusion on our blood donor lists. This outcome would be particularly disastrous for our practice of maintaining a special list of donors with rare blood types and calling them when there is an urgent need to match a special patient who also has a rare blood type.
- Donor recruitment is one of many expenses associated with supplying hospitals and other health care providers with blood and blood products. The Red Cross will not be able to pay the anticipated user fees and additional expenses for maintaining the "scrubbed" blood donor lists without passing along at least some of those costs or reducing other expenditures such as research for new testing and treatment technologies.
- Additionally, the FTC telemarketing rulemaking could also require the Centers for Medicare and Medicaid Services, the Federal Agency that oversees these programs, and private **party** insurers, to increase expenditures for blood. This could further increase national expenditures and place additional economic burdens on the public at a time when both the federal government and private employers providing health insurance are diligently seeking fiscal restraint.

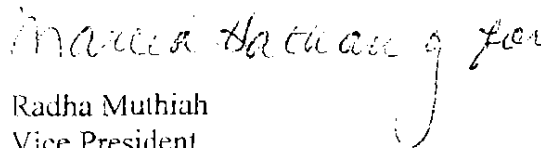
Conclusion

On behalf of the American Red Cross, thank you for the opportunity to comment on the proposed rule. We hope these comments are constructive in providing insight into the potential impact of these regulations on the American Red Cross and on the nation's blood and tissue supply. If you have any questions, please contact one of us, or Anita Ducca, Director, Regulatory Affairs, Policy and Promotion at 703-312-5601

Sincerely,



Gary Dolch, Ph.D.
Senior Vice President
Quality and Regulatory Affairs
Biomedical Services



Radha Muthiah
Vice President
Donor Strategy
Biomedical Services

Attachments

April 9, 2002

Office of the Secretary
Rm. 159
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

**RE: Notice of Proposed Rulemaking to Amend the Federal Trade
Commission's Telemarketing Sales Rule, 16 CFR Part 310 [67 Fed.
Reg. 4491; Jan. 30, 2002]**

This letter is to provide public comments on behalf of the American Red Cross regarding the *Notice of Proposed Rulemaking* (Rule or Proposed Rule) to **Amend the Federal Trade Commission's** (Commission) *Telemarketing Sales Rule* (TSR). Our comments will address the national "do not call" registry, potential changes to the TSR resulting from language contained in the USA PATRIOT Act, and the use of predictive dialing.

The American Red Cross is dedicated to saving lives, easing suffering and restoring hope at home and around the world. The Red Cross annually mobilizes relief to the victims of more than 67,000 disasters nationwide and has been the primary supplier of lifesaving blood and blood products in the United States for more than 50 years. In the year 2000, the Red Cross trained almost 12 million people in vital lifesaving skills and delivered more than 21 million locally relevant community services. The organization also assisted international disaster and conflict victims in close to 40 locations around the globe, and its emergency communication centers processed 1.2 million calls in support of U.S. military families. All American Red Cross assistance is free, made possible by voluntary donations of time, blood, and money from the American people.

We are an independent, not-for-profit organization that relies primarily on the generosity of the American people, corporations and foundations for support. In FY2000, the Red Cross channeled \$2.2 billion worth of assistance to people through Armed Forces Emergency Services, Biomedical Services, Disaster Services, Health, Safety and Community Services and International Services—all made possible by the American public.

Changes to the TSR

Under the Rule, the Commission is proposing to modify the TSR by creating a centralized national “do not call” registry (Registry). This Registry would enable consumers to eliminate most telemarketing calls simply by making one call to the Commission.

The Proposed Rule also proposes changes to the TSR mandated by the recently enacted USA PATRIOT Act. Prompted by the events of September 11, this legislation, among other things, directs the Commission to expand the TSR to cover calls made to solicit charitable contributions. Currently, the TSR covers only calls made to sell goods and services. By law, non-profit charitable organizations are exempt from the FTC’s jurisdiction and the USA PATRIOT Act does not change this status. However, the USA PATRIOT Act does enable the FTC to act against for-profit companies that engage in fraudulent, deceptive, or abusive practices when they solicit charitable contributions on behalf of charities or purported charities.

Finally; the Commission is seeking to clarify that the use of predictive dialers that result in “dead air” violates the TSR.

The National “Do Not Call” Registry

Based on the exemption of non-profit entities from the FTC Act (15 U.S.C. 45(a)(2)) it is the understanding of the American Red Cross that we are not required to comply with any of the requirements of the TSR when solicitations for charitable contributions or blood donations are made by Red Cross employees or volunteers. It is also our understanding that the Red Cross would continue to enjoy this exemption regardless of any future changes that might be made to the TSR as a result of the Proposed Notice. Thus, the Red Cross would not need to access a national “do not call” registry if calls for charitable contributions or **blood** donations were made by Red Cross employees or volunteers.

We are requesting clarification that solicitations made by Red Cross employees or volunteers would not fall under the jurisdiction of the FTC, the requirements of the existing TSK, or modifications made to it resulting from the Proposed Notice. As such, the Red Cross would not need to access a national “do not call” list.

USA PATRIOT Act and changes to the TSR

Section 1011(b)(3) of the USA PATRIOT Act amends the definition of “telemarketing” that appears in the Telemarketing and Consumer Fraud and Abuse Prevention Act (15 USC 6106(4)) by expanding such definition to cover any “plan, program, or campaign which is conducted to induce...a charitable contribution, donation, or gift of money **or any other thing of value**, by use of one or more telephones and which involves more than one interstate telephone call...” (emphasis added). **As** a result, for-profit vendors who solicit charitable contributions and donations of blood for the American Red Cross might fall under the jurisdiction of the FTC and, therefore, the TSR.

From the time a donor gives blood until the time a patient in need receives it, hundreds of steps must occur. Blood is donated voluntarily from one person to help save a life. Thus, blood donations are given freely. There *are*, of course, costs associated with collecting, testing, processing and distributing blood donations to hospitals. To recover these costs, the Red Cross and all not-for-profit blood centers must charge fees to hospitals. These fees are designed to recover costs and to invest in capital improvements to ensure there is up-to-date equipment, facilities, trained staff and much more within the confines of a non-profit organization. However, the voluntary donation, itself, is given freely.

The American Red Cross believes that calls to solicit blood donations do not fall under the language in the USA PATRIOT Act because blood donations are not a “thing of value” in a fiduciary sense. **As** a result, requests made by **the** Red Cross or its for-profit vendors for blood donation should not fall under the jurisdiction of the FTC.

Additionally, state “blood shield” laws, where applicable, generally exempt blood, tissue, and organ donations from product liability claims, including strict liability or breach of implied warranties. A majority of states have accomplished this goal by enacting statutes that define blood and tissue collection activities as medical services. Blood components intended for transfusion have been almost universally exempted from consideration as a sale of a product because of their unique status. It is defined under federal statutes, and regulated by the Food and Drug Administration as a biologic as well as a drug, requiring a physician’s prescription (see., e.g. 21 CFR 600.3(h) and 607.3(b)). Furthermore, because of the unique nature of blood donations and the need to ensure an adequate blood supply it surely could not have been the intent of Congress to inhibit or otherwise impair the ability of non-profit blood centers to make calls to request voluntary blood donations.

- **We** are requesting clarification that solicitations made **on** behalf of the Red **Cross** **by** for-profit companies for **blood** donations **would not fall** under the jurisdiction **of** the **FTC**, **the** requirements **of** the existing TSR, or **modifications** made **to** it resulting from **the** Proposed Notice.

We **are** also requesting clarification **that** for-profit vendors calling **on** behalf **of** the **Red Cross** **would** **not** **need** **to** access a national “do not call” registry. Requiring **for-profit** vendors to access a national “do not call” list **to** remove names from their list **of** individuals **to** contact, will surely reduce the ability **of** such centers **to** collect blood. **This** will **have** a direct and **profound** impact **on** the safety of patients **who** require this life-saving product.

Predictive Dialers

Certain units of the American Red Cross and some of its for-profit vendors currently use “predictive” or “automatic” dialers and pre-recorded messages to contact previous blood donors. These calls are performed to encourage future blood donations. We also use these techniques to remind donors of appointment commitments, thank donors for their participation in the blood donor program, and other similar activities that promote a relationship with a blood donor. As noted above, the supply of blood in the United States is often fragile. We have used predictive dialing techniques and pre-recorded messages

to enhance our ability to obtain blood that is needed every day to save lives throughout this country. It is an efficient, cost-effective, and proven method *to* encourage donations. Presently, only 5% of eligible individuals in this country donate blood. Even those who make an appointment to donate often fail to show up for their donation.

As noted above, blood donations are given freely and are not considered a “product” or “thing of value”. The Red Cross believes that use of these methods by the Red Cross or our for-profit vendors would not fall under the FTC’s jurisdiction.

We are requesting clarification that the use of predictive dialers and prerecorded messages made by the Red Cross, or on behalf of the Red Cross by for-profit companies, For blood donations would not Fall under the jurisdiction of the FTC, the requirements of the existing TSR, or modifications made to it resulting from the Proposed Notice.

‘[heRed Cross would like to thank the Commission for the opportunity to provide comments. We hope our views and requests for clarification will serve as constructive input during the future rulemaking process. If you have any questions please contact me at (202) 639-3031.

Sincerely,

Kurt Kroemer
Director, Regulatory Affairs
Government Relations Department

American Association of Blood Banks
Jennifer Garfinkel
301-215-6557

America's Blood Centers
Scott Caswell
202-654-2910

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Blythe Kubina
703-X07-5275

Kate Fox
American Public Health Association
202-771-2435

Alicia Mitchell
American Hospital Association
202-626-2339

News Release

BLOOD BANKING AND PUBLIC HEALTH LEADERS ISSUE A UNITED, IMMEDIATE CALL FOR BLOOD DONATIONS

*Eligible donors are encouraged to make an appointment to give blood today
and every two months thereafter –*

WASHINGTON (June 25, 2002) -- In an attempt to generate much needed blood donations, the nation's blood banking and public health leaders have joined together to issue a call for all eligible Americans to give blood this summer. The appeal comes in the face of increasingly significant blood shortages, leaving certain parts of the country with less than a one-day supply.

The American Association of Blood **Banks (AABB)**, America's Blood Centers (ABC), the American Red Cross, as well as the American Hospital Association and the American Public Health Association join in this appeal.

"To avert a critical blood shortage in certain areas of the country, we need people in these affected areas to schedule an appointment to donate blood this summer," said Karen Shoos Lipton, chief executive officer of AABB. "To ensure an adequate national blood supply in the future, we need people to donate blood on an ongoing basis. The fact that all blood organizations are joining in issuing this message underscores the importance of this matter."

Nearly one-half of Red Cross Blood Services regions and one-third of ARC-member blood centers are currently suffering from shortages and anticipate severe blood shortages in the coming weeks if people do not donate. On any given day, an average of 34,000 units of red blood cells are needed for patients in the United States. Less than five percent of the eligible population donates blood.

Reasons for the shortage include an increase in blood donor restrictions and misperceptions as to the need and use of blood in America. (See attached Blood IQ poll.)

"The public health of the United States would be in severe jeopardy without a safe, available blood supply," said Dr. Mohammad Akhter, executive director of the American Public Health Association. "Through the power of collaboration, the healthcare and blood banking communities are committed to ending the sporadic blood shortages by increasing Americans' awareness of the every day critical need for blood."

- more

Those interested in donating blood may call one of the following numbers for more information and to schedule an appointment:

- American Association of Blood Banks 1-866-FROM-YOU (1-866-376-6968)
- America's Blood Centers 1-888-USBLOOD (1-888-872-5663)
- American Red Cross 1-800-GIVE-LIFE (1-800-448-3543)

Public Health Leaders from Industry and Government Express Support for Blood Donations

Dr. Eve Slater, Health and Human Services Assistant Secretary for Health:

"The blood supply is a critical component of our health system, and it has to be constantly available in order to respond to any emergency at any time. Now, at the beginning of the summer, we need to remember that while many of us take a vacation at this time of year, the need for blood does not. That is why Americans must continue to donate blood throughout the summer vacation period, this year and every year."

Dick Davidson, President, American Hospital Association:

"Ensuring a safe and adequate supply of blood is important to all Americans. Nowhere is this more evident than in our nation's hospitals. That's why **we** encourage Americans who can to donate blood today during this critical shortage as well as tomorrow."

Video News Release Available

FEED DATE: TUESDAY, JUNE 25, 2002

FEED TIME: 2:00 - 2:30 PM ET

COORDINATES: C-BAND: AMC 2 (C) /TRANSPONDER 1 /AUDIO 6.2 & 6.8

DL PREQ: DL FREQ: 3720 (V)

RE-FEED DATE: WEDNESDAY, JUNE 26, 2002

RE-FEED TIME: 10:00 - 10:30 AM ET (FED IN ROTATION)

COORDINATES: C-BAND: TELSTAR 5 (C) /TRANSPONDER 16 /AUDIO 6.2 & 6.8

DL FREQ: 4020 (H)

FORMAT: Package TRITBA
SOTS
B-roll

Featured Spokespeople:

- Karen Lipton, executive director of American Association of Blood Banks
- Dr. Mohammad Akhter, executive director of the American Public Health Association
- Dr. Christina M.S. Johns, M.D., pediatric Emergency Medicine specialist at Holy Cross Hospital and Children's National Medical Center

America's Blood I.Q. Poll

One reason for the reoccurring shortages is widespread misperceptions about America's blood supply. According to a recent nationwide telephone survey of 1,005 adults 18 and older by StrategyOne, most Americans lack basic knowledge about blood donations:

- Americans *underestimate* the country's need for blood transfusions. (Only nine percent of respondents knew blood is needed every two seconds.)
- The majority of adults *overestimate* the number of people who actually donate blood. (Only eight percent of those polled knew less than five percent of all eligible donors give blood.)
- About one in four Americans (23 percent of respondents) knows that U.S. adults are allowed to give blood every two months.

Annotated Questionnaire

1. *How often are American adults allowed to give blood? Would you say they are allowed to give blood...*

Responses	Percent of Respondents
Once a week	6%
Once every two weeks	8%
Once every month	25%
Once every two months	23%
Once every <i>six</i> months	13%
Once every nine months	2%
Other	2%
Uncertain/ don't know	22%

2. *In an average year, what percentage of the eligible U.S. population donates blood?*

Responses	Percent of Respondents
4 or less	11%
Five	8%
6-20	29%
Over 20	28%
Uncertain/don't know	23%

Appeal for Blood Donations
Page Four

3 *On an average day, how often does someone in America need a blood transfusion? Would you say that someone needs a blood transfusion...*

Responses	Percent of Respondents
Every second	11%
Every two seconds	9%
Every twenty seconds	17%
Every ininute	21%
Every two minutes	16%
Every twenty minutes	15%
Other	1%
Uncertain/ don't know	8%

4 *How many major blood types ure there?*

Responses	Percent of Respondents
1	*
2	2%
3	16%
4	38%
5	15%
6	8%
7	2%
8	4%
9	*
10	1%
15	*
35	*
50	*
53	
96	
Uncertain/ don't know	13%

5 *What is the minimum age requirement for giving blood?*

Responses	Percent of Respondents
Sixteen or under	14%
Seventeen	5%
Eigh tern	62%
Nineteen or older	5%
Uncertain/ don't know	13%

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